IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This document relates to: *All Actions*	MDL No. 19-2875 (RBK)

[PROPOSED| SPECIAL MASTER ORDER NO. __

THIS MATTER having been brought before the Court by way of the Motion to Seal Pursuant to Local Civil Rule 5.3 (the "Motion to Seal") filed by Defendants Teva on notice to liaison counsel for Plaintiffs; and the Court having considered the Parties' submissions and proposed sealed information, and the factors contained in Local Civil Rule 5.3(c)(2); and the Court having further found that the standards set forth therein have not been met, the Court makes the following Findings of Fact and Conclusions of Law:

1. Judicial documents, such as the documents appended in support of (or in opposition to) the overall class certification briefing, are entitled to a presumption of public access. *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019). As the *Avandia* Court held, "the more rigorous common law right of access

[applies] when discovery materials are filed as court documents." *Id.*

2. While Rule 26 permits the use of protective orders to designate these documents as confidential when produced during discovery, the standard is different than the inquiry a Court must engage in prior to sealing the same documents when they become judicial documents. The public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access. *Avandia*, 924 F.3d at 670; *see also* D.E. 1269, p. 7.

3. This is especially true here, in assessing judicial documents that are being offered in support of the proposed certification of a class action. The Third Circuit has previously held that the right of public access is particularly compelling in class cases because "many members of the "public" are also plaintiffs in the class action*" Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 193 (3d Cir. 2001). Allowing the right to access judicial documents (such as those appended to the Class Plaintiffs' Motions), promotes confidence in the "administration" of the Class Members' case. *Id.*

4. Because there is a presumption in favor of access for these judicial documents, the burden requires Teva to demonstrate that the "material is the kind of information that courts will protect, and that disclosure

will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 678 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994)).

5. While certain trade secrets or highly commercially sensitive information may overcome the public right of access, that is not to say that trade secrets or confidential commercial information are entitled to an "absolute exception" from public access. *Cole's Wexford Hotel, Inc. v. Highmark, Inc.*, No. 2:10-cv-01609-JFC, 2019 U.S. Dist. LEXIS 142214, at *37 (W.D. Pa. May 31, 2019). Furthermore, merely confidential business information is not entitled to the same level of protection from disclosure as trade secret information. *Littlejohn v. BIC Corp.*, 851 F.2d 673, 685 (3d Cir. 1988).

6. Additionally, not all commercial harms or financial losses are entitled to protection from disclosure. These includes potential commercial harms that might stem from embarrassment and injury to corporate reputation (*Avandia*, 924 F.3d 662, 672), or information that may cause the value of stock to decline does not override public access (*Littlejohn*, 851 F.2d at 685), or even information related to poor corporate management (*Publicker Indus., Inc. v. Cohen*, 733 F.2d

1059, 1074 (3d Cir. 1984)).

7. In terms of the articulated compelling and countervailing interests against disclosure, "specificity is essential." *Avandia*, 924 F.3d at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194). "Broad allegations of harm, bereft of specific examples or articulated reasoning, are insufficient." *Id.*

8. Moreover, the Court has already rejected affidavits proffered in this case that contain conclusory and unspecified statements of "harm" in conjunction with the sealing inquiry. *In re Valsartan N-Nitrosodimethylamine (NDMA)*, 512 F. Supp. 3d 546, 553 (D.N.J. 2021). These include conclusory statements regarding generalized "allegations of injury to reputation and client relationships or the embarrassment that might result," or statements that the authors and recipients of the documents expectation that the documents would remain confidential, because "large swatches of routine emails would be kept under wraps." *Id*.

9. Upon a review of the clearly defined and serious injury, the District Court must articulate the compelling, countervailing interests to be protected, and make "specific findings on the record concerning the effects of disclosure." *Avandia*, 924 F.3d at 672-73 (quoting *In re*

Cendant Corp., 260 F.3d at 194). As such, any affidavit must be analyzed in conjunction with an independent review of the at issue documents, because, as Judge Schneider previously stated, the Court "is not required to give credence to [a] conclusory self-serving affidavit that is inconsistent with the Court's independent review of [the] documents." *In re Valsartan N-Nitrosodimethylamine (NDMA)*, 512 F. Supp. 3d 546, 553 (D.N.J. 2021).

10. The temporal posture of the parties must also be assessed. As the Third Circuit held in Avandia, "[s]ealing must be based on *current evidence* to show how public dissemination of the pertinent materials *now* would cause the competitive harm." *Id.* at 678 (quoting *In re Cendant Corp.*, 260 F.3d at 196) (emphasis added).

11. Teva claims that the "disclosure of [TEVA-MDL2875-00049024] would cause irreparable harm to Teva by providing its competitors with direct insight into Teva's internal processes for investigating, evaluation, correcting and mitigating the presence of nitrosamine impurities." Binsol Decl. at 4. However, these were not processes and evaluations that Teva decided to conduct on their own -- Teva was required by the FDA to conduct these investigations and evaluations. Moreover, these evaluations were not only conducted by Teva, but

they were also conducted by every drug manufacturer across the world who manufactured ARBs.

12. Much like with the evaluations and investigations that were required to be conducted under cGMPs, Teva's post hoc investigation into the toxicology of the nitrosamine impurities was likewise an investigative process required by world regulators after the discovery of the contamination. In guidance, the FDA requires that a drug substance manufacturer employ established risk management strategies and assess the theoretical increase in risk, which would result in investigative documents like those which Teva is now claiming in some internal proprietary practice.

13. Contrary to the assertions contained in Mr. Binsol's declaration, these cancer risk assessments Teva conducted are well "established" throughout the industry (and not some commercially sensitive process proprietary to Teva). *Id.* They are predicated on much of the same information and secondary sources Teva used in their risk assessment.

14. While Teva claims that disclosure of communications regarding their audit of ZHP, an API supplier, would cause "irreparable harm to Teva by providing its competitors with internal thought processes of Teva

leadership concerning an internal audit as well as Teva's internal reporting processes." However, this auditing and internal reporting of the auditing processes are, again, practices and activities which are part of the activities manufacturers are required to conduct as part of cGMP and not a proprietary activity of Teva.

15. Mr. Binsol's Declaration is replete with sweeping statements regarding the competitive harm Teva would suffer. However, Mr. Binsol fails to credibly articulate how and why information regarding Teva's compliance (or non-compliance) with public guidelines and regulations regarding cGMPs would actually be competitively harmful. Mr. Binsol's affidavit is further undercut by the fact that Teva has disclosed much of the information it now claims is competitively sensitive to industry partners in webinars and talks.

16. If the implicit implication in Mr. Binsol's affidavit is that knowledge of Teva's poor management in complying with and abiding by the global regulations and guidance is somehow competitively sensitive, as further discussed *supra*, information about poor management is not enough to overcome the presumption of public access.

Pursuant to the foregoing Findings of Fact and Conclusions of Law:

It is hereby ORDERED this ___ day of _____, 2022 that Teva's motion to seal the above materials is **DENIED**,

/s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master